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Intellectual Property Rights Regime and Creation of Innovation Based Enterprises in India

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1. Introduction

In recent years, the Indian government has undertaken significant modifications in the Intellectual Property (IP) regime of the country. Some of the key elements of the modified policy having major implications for several sectors in the economy, especially the pharmaceutical, chemical, biotechnology and information technology related sectors. Given the changes in the IP regime, the competitive landscape of many of these sectors is undergoing a fundamental change in India. This has led to a realignment of business strategies by firms in these sectors in order to face the challenges thrown up by the changing regime, as companies which enjoyed protection under Indian IP laws will have to adapt to India's accession to WTO (TRIPS) norms in 2005. At the same time, globalization of the Indian economy is opening up new opportunities for firms in the country and they will need to build strategies to exploit the emerging opportunities.

IP regimes in a country play an important role in fostering the direction and the quality of entrepreneurial innovation across all sectors of the economy. For example, an IP law that fosters incremental innovation can allow small businesses to benefit by affording protection to small incremental improvements on existing intellectual property that can in turn be used by owners of the IP to move up the technological value chain. In addition, the IPR framework directly affects the ability of entrepreneurs to take advantage of commercial opportunities that require the existence of a suitable IP regime before commercial/service agreements can be reached with potential clients. Such market creating potential of the IPR framework can also impinge on the ability of small entrepreneurs to enter into IP intensive activities as subcontractors and licensees.

While India has made its IP regime TRIPS compatible, it is not entirely clear if the new regime would facilitate the participation of Indian companies in the knowledge intensive global production and R&D networks and if it is appropriate for an economy that is expected to grow rapidly enlarging the demand for a variety of products and services. This paper explores these issues in the context of IT-electronics and pharmaceuticals- biotechnology sectors. It is built on the premise that *ceteris paribus* participation of Indian firms in IP creation and participation in knowledge intensive activities is desirable. If changes in

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technology and global industrial structure are creating opportunities for such participation, IP policies should positively discriminate in favour of such participation. Similarly, if the domestic market for knowledge intensive activities is growing rapidly, policy makers should explore if tinkering with IP policies can facilitate the participation of local firms in this market. The paper argues that such possibilities exist and some pro-active changes in IP policies are desirable.

The rest of the paper is divided into four sections. Section 2 summarizes the emerging opportunities in the pharmaceutical-biotech sector and explores areas where Indian firms can potentially participate. The next section undertakes a similar analysis for the IT-electronics sector. Section 4 reviews the existing IPR laws to evaluate if these laws can potentially constrain the exploitation of the emerging opportunities in these sectors by Indian firms. The final section provides some concluding remarks.

2. Emerging Entrepreneurial Opportunities in the Pharma-Biotech Sectors

The innovation system in the pharmaceutical industry is very complex. The complexity of R&D, which is essentially science based, has been on the rise due to the emerging synergies in the research streams of conventional chemistry, biotechnology and information technology (IT). It is becoming increasingly important to integrate knowledge at various levels of research in biomedical sciences, pharmaceuticals and IT. Institutional factors are very important for such integration and coordination. For example, institutional coordination across disciplines between academic research labs, public sector research establishments, private industrial research units, pharmaceutical firms, CROs and hospitals will be critical for such integration to take place.

2.1 Changes in Drug Discovery Systems

Riding on the synergies between different disciplines, the drug discovery and commercialization processes are undergoing significant change. The following developments are particularly important to understand the potential changes in the innovation system of the pharmaceutical industry (see Economist, 1998 and Jungmittag et al, 2000 for details):

The shift from wet chemistry to bio-technology based processes for identifying/ developing a molecule or compound has *reduced the economies of scale*;
Combinatorial chemistry has helped develop gene libraries that can be hired for screening resulting in significant *reduction in the entry barriers in initial screening business*;
Computer aided development of molecular designs is used to filter molecules and compounds for testing with wet chemistry. This biotechnology-software interface has meant *higher success rates and speedier selection of compounds*;
Actual drugs are being designed with the help of computers. Software are *used to reduce uncertainty in drug development;*
New technologies in pre-clinical development are reducing the drug development cycle. For example, cassette dosing and simultaneous optimization of toxicity, bioavailability and pharmacokinetics has reduced the time required for clinical trials. *Service firms have emerged to do such trials;*

Computerized safety and efficacy trials conducted on patients avoid useless regimes to reduce number and size of trials. This saves time and money. These new technologies have also *facilitated the emergence of contract research organization (CROs).*

Appendix I provides an overview of the drug discovery and development process today. This chart along with the changes listed above identifies a variety of entrepreneurial opportunities. Overall, these technological developments have created a situation where drug discovery and development may no more be dominated by large vertically integrated enterprises. Decline in entry barriers in several segments can lead to disintegration of this process. Given good access to software, biotechnology and wet chemistry based skills, many firms in India are well placed to occupy several spaces in this value chain. However, a favourable IPR regime and good implementation of the IP laws may be essential for these firms to participate in decentralized drug discovery & development process where several firms perform highly specialized tasks. This would be particularly so if the entry into these niches is innovation based or if it involves use of protected technologies. With the impending changes in the IPR regimes, Indian firms will need to identify their niches and create appropriate capabilities for occupying these niches. A favourable IPR regime combined with the above mentioned technological developments and the associated uncertainties might also lead to creation of networks and alliances between firms having diverse capabilities on the one hand and educational institutions & public sector entities on the other.

2.2 Emerging Strategies for Pharmaceutical Firms

These changes in the drug discovery processes and the emerging liberal policy environment will have significant implications for the innovation system in the pharmaceutical sector and for the strategies adopted by firms in this sector, especially small ones. Moreover, from the perspective of the transnational corporations, three strategic changes are expected to take place[2]:

- FDI in overseas manufacturing may increase with special focus on contract manufacturing of drugs (even the ones that are still on patent);
- More on more pharmaceutical firms may locate part of their R&D activities in India through R&D centres or through outsourcing of technological activities; and
- The research portfolio of MNCs may shift (at least marginally) in favour of diseases relevant for the developing countries, especially those that have large populations with reasonable ability to pay. Such a shift would require specialized skills of firms, individuals and R&D institutions in developing countries like India.

Admittedly, the strategies that the MNCs would adopt for countries like India will depend on a variety of factors, including the availability of skills and capabilities as well as the nature of regulation and competition in the host countries. A systematic exploration of these strategies and their linkages with regulation and the innovation system would be useful. A proactive regulatory structure can, in fact, facilitate the exploitation of these strategic opportunities by

[2] Examples in IVCJ (2006) and Banerji and Bhatia (2004) show that these strategies are already been used.

Indian pharmaceutical, biotechnology and IT companies. An appropriate IP regime, for example, may not only help exploit the opportunities created by the changes in drug development technology and the emerging structure of the pharmaceutical and biotechnology sectors but also help respond effectively to the emerging R&D and production strategies of the MNCs. We may gain a great deal if India becomes a hub for R&D and manufacturing related sub-contracting in these sectors. Preliminary explorations suggest that pharmaceutical firms in India are exploring the following options (Table 1)[3]:

- Develop new pharmaceutical products. So far, the trend is that firms find new chemical entities, patent them in major international markets, develop them up to a point and then license them to MNCs for further developments and clinical trials (G*row and sell* strategy);
- Focus R&D on drug delivery mechanisms, dosage forms and bio-enhancers to improve the efficacy of existing patented drugs. Once this is achieved, cross licensing possibilities with the patent holder of the drugs that are affected by these inventions can be explored;
- Focus on process R&D for patented drugs to acquire process patents and explore cross-licensing/ licensing options. These process inventions are also very useful once the drug gets off patent;
- Build alliances with biotech and IT firms and also with educational institutions to develop new technologies for pharmaceutical research. IT firms are also gradually entering into the health domain;
- Focus on contract manufacturing of patented drugs;
- Focus on drugs, which are going to be off patent in the near future. This strategy is particularly being followed to enter developed country markets as soon as the relevant patent expires;
- Produce drugs that are off patent today; and
- Combine some of these strategies with co-marketing/marketing arrangements.

Table 1
Emerging Strategies of Indian Pharmaceutical Firms

Strategy	Companies
A. Supply Partner/Sourcing Base	
A1. API, Intermediates, Dosage Forms	Cipla, Biocon, NPL, Dishman, Cadila
A2. Contract Research & manufacturing	
A21. Contract manufacturing (CMO)	Shasun, Jubilant, Dishman, Cadila, Syngene
A22. Contract Research (CRO)	Vimta labs, Clingine
B. Generic Manufacturing	
B1. Para II/III Generics	Ranbaxy, Dr Reddy's, Sun Pharma, Wockhart, Cadila
B2.Patent Challengers	Ranbaxy, Dr Reddy's, Sun Pharma
C. Innovator	
C1. New Drug Delivery System (NDDS)	Ranbaxy, Cipla, Sun Pharma
C2. New Chemical Entity (NCE) Research	Ranbaxy, Dr Reddy's, Sun Pharma, Glenmark

Source: IVCJ (2006), p. 23

[3] Basant (2005) and Banerji and Bhatia (2004) also provide examples of firms that are adopting these strategies.

That the scope for contract manufacturing is high can be gauged by the fact that India has more than 70 FDA approved drug manufacturing plants and over 200 Good Manufacturing (GMP) compliant manufacturing plants (IVCJ, 2006). It is evident that the IP regime and its implementation will affect most of these strategies. This will be particularly the case with respect to product patenting, data exclusivity etc. As mentioned, within the first strategy, the firms may have different options. The inventing company may not manufacture the product it has developed; it may not even conduct expensive trials required before commercialization of the drug. The company can *grow and sell* its product to another company that will conduct trials, manufacture and commercialize the product. Apparently, the licensing arrangements are proliferating because the costs of taking an invention from conception to market are escalating. Laboratory work and a series of trials and pilot projects follow basic research. Only when the trials are successful, can the drug be commercialized. At each stage, the costs and risks increase exponentially and so it make sense for Indian firms, who have limited resources but an abundance of low-cost and highly trained scientists, to focus on basic results and license the results. *Grow and sell* strategy can potentially exploit relatively inexpensive research skills of Indian scientists without taking undue risks. Very few firms may, however, have the product development and licensing skills and capabilities to implement this strategy. Exploitation of relatively inexpensive research skills and process capabilities that have been acquired over the years may be more feasible, if a firms wishes to opt for an R&D intensive strategy. The other strategies to exploit emerging niches in drug discovery, drug delivery, process innovations etc. may be more relevant for relatively smaller enterprises.

Unfortunately, no systematic assessment has been made of the links between these strategies and IP regimes. A detailed analysis of the IP needs for the exploitation of such opportunities is critical. However, apart of the examples listed in Table 1 and Appendix II, a few more examples suggest that Indian firms are exploiting some of the emerging opportunities and benefiting from them:

- Matrix Laboratories developed a non-infringing process for the blockbuster anti-depressant, the $1.5-billion Citalopram. Lundbeck, a Danish pharma company and the Originator, made a $40-million offer - nearly half of Matrix's annual revenues - for this manufacturing process.
- Hyderabad-based Avon Organics developed the biotechnology process for pseudoephedrine (an off-patent raw material cold formulations and syrups) and its derivatives, with GlaxoSmithKline (GSK). Ever since Avon changed its strategy from a general API (active pharmaceutical ingredient) supplier to a friendly API supplier in 1996, its revenues have grown from Rs. 16 crore to Rs. 90 crore today.
- Moreover, while the jury on whether a new use or dosage form (formulation) patent extend the term of the patent granted on the original molecule is still out (see discussion in Section 4), some Indian firms have started to benefit from it. Bayer patented ciprofloxacin in 1983 and its patent expired in 2003. As such others were free to research and study the molecule. The research by Ranbaxy led to the development of a once-a-day oral dosage form, which increases patient compliance and convenience. Bayer bought the product development and global marketing rights from Ranbaxy for a fee of over $65 million. Ranbaxy will also receive up to 10 per cent royalties on sales.

Most of the research-based firms believe that a more stringent IPR system will create newer opportunities for the Indian firms. It is argued that during the pre-TRIPS period, the Indian pharma industry developed unique skills in chemistry and biochemistry. Now, Indian companies can compete effectively with global majors in developing new salts, new derivatives, new uses, new dosages and new delivery systems. In fact, according to the PCT database, Indian companies have filed approximately 4200 applications. Of these applications 55 per cent are for pharmaceutical incremental innovations. For instance, Ranbaxy has filed 239 patent applications of which 122 are for derivatives, formulations, compositions and new dosage forms. Most of Ranbaxy patent applications are for incremental innovations

2.3 The Biotech Factor

The above-mentioned research based opportunities have multiplied with the growth of biotechnology in India. According to some estimates, there are about 800 biotech related companies, with 96 firms exclusively working with biotechnology. With beginnings in fermentation and enzyme production, the industry has now grown to about $ 1.07billion and covers new drug discovery, bio-informatics, clinical research and synthetic chemistry. About 230 biotech-based drugs are already in the market covering 13 therapeutic segments (IVCJ, 2006; 28). Moreover, genomic research, bio-generics and stem cell research are adding fresh opportunities for growth.

2.4 Convergence of Pharma-Biotech and IT Technologies

With technological change, several new opportunities for IT firms to work on the boundaries of other sectors like the pharmaceutical, biotechnology, and auto are becoming available. It is becoming increasingly important to integrate knowledge at various levels of research in biomedical sciences, pharmaceuticals, and IT. Riding on the synergies between different disciplines, the drug discovery and commercialization processes are undergoing significant change. Based on the changes in the drug discovery systems discussed earlier, several opportunities seem promising. Increasing use of combinatorial chemistry to develop gene libraries that can be hired for IT based screening will result in significant *reduction in the entry barriers in initial screening business.* Besides, computer aided drug design, use of IT in pre-clinical trials and computerized safety and efficacy trials also provided new entrepreneurial opportunities. All these domains are very IP intensive and would require a more proactive participation of Indian firms in IP protection. This will obviously lead to enhanced participation of these firms in IP generation and creation. There is evidence to show that Indian IT firms are increasingly exploiting these domains as well.[4]

3. Emerging Entrepreneurial in the Indian IT and Electronics Industries

The Indian IT industry is undergoing a major change. Despite concerns on the contrary, one can see a shift towards more value added services, an emerging specialization in embedded

[4] Strand Genomics, a spin out firm from a well-known institute of science education (Indian Institute of Science, Bangalore) is a prime example of this trend. Other firms active in this domain include Agilent Technologies (Life Sciences and Chemical Analysis), Wipro Health Science, SysArris Software and Kshema Technologies.

software and even a marginal shift towards products. The opportunities for IT firms to work on the boundaries of the pharmaceutical and biotechnology sectors have already been highlighted. There is also a belief that in future, major market growth in IT would take place in Asia, especially in India and China. Consequently, firms will need to create IT products that satisfy the specific needs of these markets. When this trend picks up, the Indian IT firms would find themselves much closer to the market and would be able to respond better to the emerging market needs than firms that are located elsewhere. One of the problems, Indian firms have faced vis-à-vis product development has been the "distance from the market". Lack of proximity to the large western markets where the IT products currently sell has put them at a disadvantage. Such a disadvantage may get reduced if the local markets pick up. The IP regime needs for the sector need to be seen in this context.

Technologies underlying the IT industry are changing very rapidly. In many instances, these technological changes bring in possibilities of a change in the global industrial structure. While there are many instances of this type, we will focus on a few to highlight the potential impact on IPR needs of Indian IT firms.

3.1 Insights from Embedded Software/Services Industry[5]

New technologies have modified global production networks significantly in the area of semi-conductors in recent years. Similarly, the munificence of IT based technologies across a variety of sectors has spawned several new technological and economic opportunities. It is argued that changes in these technologies and the associated changes in the industrial structures are likely to throw up new entrepreneurial opportunities for Indian IT firms which might require a different perspective on IP related issues.

With the advent of System on Chip (SoC) integration in this industry, the strategic options of firms have changed.[6] As SoCs become larger and more complex, it will become difficult for firms to remain competitive in all the functional design elements that are being integrated into the SoC. An emerging solution for this problem is the fast growing market of design modules (DM) licensed out by small, specialized firms. This change can potentially 'disintegrate' the semi-conductor industry providing niche opportunities for small firms. According to Linden and Somaya (2003), this shift can be quite significant:

> The emerging SoC-based industry structure typifies the historical shifting between integrated and ever more fragmented organizational modes of production in the electronics industry. Just as specialization in components proliferated in the PCB-based electronic systems, the SoC era is showing signs of industry fragmentation driven by specialization in the disembodied semiconductor designs that are being licensed between firms. (Linden and Somaya, 2003).

Recent studies (see, for example, Bhuyan, 2002) and the information summarized in Appendix II show that many Indian firms are already active in this emerging domain and are

[5] This subsection is largely based on Goyal and Sharma (2004).
[6] For detailed discussion of this issue, see Linden and Somaya (2003)

participating in the emerging networks of SoC creation. India may have missed the IC manufacturing opportunity; it sure can exploit this new opportunity. But, this will require sharper focus on IP and a more active participation in standards creation, as that will drive the creation of markets in this sector.[7]

The *embedded devices ecosystem* consists of firms in embedded products and services segments. This consists of OEM's such as Nokia and IBM that design and produce products like mobile phones and laptops. These products contain features (e.g., computing, graphical image processing, audio and speech encoding/delivery, and wireless connectivity) that are powered by semiconductor chipsets (platforms) developed by large MNCs like Texas Instruments, Intel, Siemens etc. Embedded software applications are developed to leverage the power of the processor platform for customer specific applications. There exist electronic design automation firms (EDA) like Cadence and Synopsis, which create software tools to accelerate the hardware and embedded application design tasks. Finally, there are services firms that leverage their knowledge of the embedded software tools, EDA tools, processor platform architecture, and customer requirements to develop embedded software applications for their customers. *Indian firms are essentially located in the last segment and provide design services. These firms include Wipro, Sasken, Mindtree Consulting, Tata Elxsi, HCL Technologies, etc. (Goyal and Sharma, 2004).*

Within design services, three levels can be distinguished: device level, module level and system level. Within *device* level, design services provided by Indian firms are broadly divided into: (i) front-end design, (ii) design verification, (iii) physical/back-end design and (iv) chip deployment services. Of these, the bulk of the work coming the way of Indian service firms is in design verification. Recently, Indian firms have moved up the value chain, into front-end design of complex Application Specific Integrated Circuits (ASIC's). As mentioned, designing a SoC system where the processor, memory and all peripheral components are housed on the same silicon chip is very complex to design. But some Indian firms have been able to enter this design market as well.

There are many Indian companies involved in *module* design, for customers in India as well as overseas. This involves designing a multi-component circuit implemented on a printed circuit board. If design services provided to Indian firms are included, then module level design is the area in the embedded services industry that has the highest volume of work by revenues. For example, there are thousands of small module design and fabrication firms that cater to the domestic automobile, consumer goods and process industries.

System Level Design is a core activity for OEMs like Nokia, IBM, Cisco, and Samsung. Hence it is typically not outsourced. There do exist large global technical services consulting firms that assist these manufacturers in designing new systems, but very few Indian firms are not engaged in either creating new systems like hand-held devices or mobile phones, nor are they active participants in the design of these services, for which they need to be much closer

[7] Linden and Somaya (2003) provide an excellent account of these strategic market-creating opportunities.

to the end consumer. However, there are some examples of firms like Sasken and Tata Elxsi, building and licensing entire system level designs, like Sasken's model development services. However, this represents a very small segment of the work done by Indian embedded services firms. The simputer was an example of a domestically designed system, but Indian firms have made few similar forays into system design.

It is important to note that each of the three design services markets (Device, Module and System), has its own value chain of activities. Indian firms operate in each service market, but the extent of participation across the value chain differs. A detailed exploration of the Device Level Design Services Market suggests that there is potential for Indian companies to participate in the value chain as a lot of work is being outsourced (Goyal and Sharma, 2004).

The development of the Indian IC design industry began in the early 1980's, when Western semiconductor firms felt a requirement to augment technical staff on their in-house design teams. This resource augmentation goes by the familiar term called 'body-shopping'. From those early days, the services industry has matured to the extent that several chip design projects have been completed entirely out of India. Three types of participants have emerged in India, to provide IC chip design services:

- Global Major's Captive Firms (TI, Intel, Analog Devices)
- Large Design Consultancy Firms (Wipro, Tata Elxsi, Sasken, Mindtree)
- Small Niche Design Firms (Wavelet Technologies, eInfochips)

Global Major's Captive firms usually provide design services that are higher in the value chain, than the large Indian design consultancies, and smaller niche design firms. All IP is owned by the MNCs and any patents for new chip design, or embedded software are typically in the USPTO. Large Design Consultancies and smaller niche design firms have not been able to participate across the design value chain to the same extent as the global major's captive units. Moreover, the Large Design Consultancies and smaller niche design firm segments differ in their approach in three different ways:

1. Firstly, the larger consultancies have skills across a wider range of processor platforms and embedded software domains.
2. Second, the large design consultancies are increasingly trying to span the design value chain from specification to silicon as it is referred to by the industry. This means that rather than target business in one or two activities in the chip design value chain like design verification, or logic synthesis, these firms are trying to execute projects where they can become involved in architecture definition, RTL Design, Verification, and Physical design.
3. Third, the larger design consultancies are also trying to create products in the form of packaged reusable design modules, also called as Silicon Intellectual Property (SIP), from the experience gained in service projects. SIP can be licensed to large OEM customers to accelerate the design cycle for these customers.

The large design consultancies have been successful in executing the first part of their strategy, because the sheer size of their engineering talent enables them to cover most processor and embedded software domains. Thus, they are horizontally spread across multiple embedded software and processor domains and provide a particular type of service in the value chain to their customers. The second and third elements of their strategy require them to go deeper into the value chain of design services, which has been a major challenge for them barriers to entry are not easy to transcend.

A review of the history of chip design services by Indian firms suggests that over the last decade, they have met *limited success in participating across the value chain*. Third party design services firms, including Indian firms have found it very difficult to participate in the front-end design portion of the chip design value chain, by receiving outsourced design work from established ASIC firms like TI, IBM, and Intel. The first exposure Indian design services firms had to VLSI/ASIC chip design took the form of resource augmentation, commonly referred to as body shopping, in the late 1980's. Design teams at large ASIC firms like TI, that were working on a new chip were sometimes short-staffed, and required *resource augmentation* in the form of trained engineers. However, in this "sub-contracting" process the original design always stayed with the company, and these engineers were made to sign non-disclosure agreements. Thus, the initial exposure that Indian design engineers had to ASIC design was on-site resource augmentation.

Outsourcing to Indian firms began in the areas of design verification and physical design as a cost saving measure. Front-end design outsourcing was very rare, because the semiconductor IC industry faces a different risk scenario, than the software industry in case design flaws are revealed after the chip has been put into production.[8] Therefore, outsourcing was resorted to only for those parts of the design chain that are less risky. Also, front-end design was an activity that was rarely outsourced, because it was the core strength of the ASIC firm developing the product, and most of the intellectual property for the chip was encapsulated in front-end design, hence firms performed this task in-house, while help was taken from third party design firms in physical design, and design verification. These are repetitive tasks, which are automated to a great degree using EDA tools. Economics, rather than skill played a major part in India receiving much of this work. After the initial round of outsourcing, involving mainly physical design and verification, Indian firms started to obtain work involving some front-end design. The work that came India's way initially was sustenance work or maintenance work. This involved providing support engineering (such as incorporating a new standard in the design) to the chip after it has been put in production. Through the early to late 1990s Indian firms that were recipients of outsourced work in physical design, and chip maintenance gained from this work and accumulated a track record of reliable services and trained man power. During the semiconductor boom in the late 1990's, several Indian engineers were trained on US client sites, and subsequently returned to India, bringing with them valuable skills and experience. Due to these factors as well as low

[8] Unlike software, where a bug-fix patch can be quickly installed, in hardware, such fixes involve product recalls, changes in design, and manufacturing, at a huge cost to the ASIC firm.

cost, when ASIC firms began to move to the next generation of a chip, or a completely new chip, they began to increase their reliance on Indian outsourcing partners, helping the Indian firms move up the value chain.

Currently, Indian chip design service firms are recipients of outsourced work involving all aspects of the design life cycle from specifications to silicon in certain commodity chips, like modems, USB, and Ethernet chip. These chips have to conform to certain IEEE global standards. They are used in a wide array of consumer electronics items, whose manufacturers may not be interested or skilled in designing and manufacturing them. The risk involved in outsourcing the development of these chips is not very high for an equipment manufacturer, because in case the project fails, back-up options in the form of off-the-shelf chips are available, although these need to be customized, and cost more. Despite all this progress however, in the near future, it seems unlikely that companies like TI, and Intel will outsource the front-end chip design activity to third parties, in India or any other country including the US. However, these companies have opened captive centers in India, where the quality of work that is being outsourced is much higher in the value chain of chip design.

The strategy followed by design services firms that are near the ASIC firms in markets like the US is different from the one being followed by Indian design firms. US based design services firms like Silicon Logic Engineering (SLE), ReShape, Qthink have moved away from trying to span the value chain, and re-focused their efforts on specific design tasks. This was necessary as ASIC design became very complex, and specialists were needed to handle specific tasks. Thus, firms that started out as small ASIC design firms spanning the value chain, sharpened their focus onto one specific step. At the same time, these firms invested in R&D for these steps and developed proprietary software tools to assist them perform these specialized design tasks for their customers. Indian firms have not made similar investments in R&D of individual steps in the design value chain. On the other hand, their strategy calls for them to expand their presence across the value chain. There are firms in the US that have followed a similar strategy of spanning the value chain of design. But the competency these firms bring is that of being nodal firms responsible for coordinating the design tasks of specialized firms on behalf of the client ASIC firm. The firm eSilicon, for instance, provides a design service that gives customers choices for the foundry, packager, and the like. The company handles all the coordination of effort and provides the oversight expertise that customers may lack. eSilicon does not try to play an active role in design tasks. These practices of US based design services firms reflect the nature of the chip design value chain as a set of specialized complex tasks, with front-end tasks handled by the ASIC firms in-house, and physical design/verification tasks outsourced to specialty firms with their proprietary automation tools. *In such a context, it would seem that Indian firms neither have the R&D muscle to develop proprietary tools for specialized design tasks, nor the nearness to customer and relationships to coordinate and integrate the workflow on behalf of the ASIC firm.*

But as chip densities increase and the resultant complex designs would require several teams to work in parallel on blocks of the design, and a need for continuous real-time coordination

among the tool developers, library, SIP, and design-service vendors, as well as foundries and process developers. This combined with the ned to accelerate the design process may seem as an opportunity for Indian design firms to get a part of the design pie, however, the need for close coordination means that Indian design teams will have to work on-site, as opposed to using the traditional outsourcing model, thereby losing the low cost advantage. Also, the industry has already seen some consolidation. For example, tool vendors are acquiring SIP and design-service vendors in order to tighten relationships as well as to expand their base businesses. It seems that large EDA vendors like Cadence stand to gain the most from these developments.

Overall, the barriers to move up the value chain for Indian firms stem from the risk and costs associated with flaws in front-end design that may be uncovered after the chip is put into production. This prevents large ASIC firms from outsourcing this key task. Besides, front-end design is a complex activity that represents a core competence of these firms, and they prefer to keep this intellectual property tightly guarded. However, intellectual property rights protection was not identified as a key deterrent to increased outsourcing, as most IPR's are acquired in the US, and are not easy to reverse engineer in the semiconductor design industry. Also design services firms sign non-disclosure agreements with ASIC clients to protect any trade secrets revealed to the design services firms.

3.2 IP Licensing as a Business Model

The IP licensing business model was identified as the third element of the Indian firms potential strategy. This might emerge as an interesting option for Silicon IP (SIP). As mentioned earlier SIP refers to reusable design modules that can be licensed from IP vendors, and incorporated into a device design. Use of SIP has accelerated because semiconductor and systems firms are under increasing pressure to accelerate their design process. While semiconductor fabrication technology as predicted by Gordon Moore has advanced rapidly, design capability and capacity has lagged. This is known as the design-productivity gap. Attempts were made to bridge this gap when specialized electronic development automation software tools were developed in the early 1980's. However, the complexity of end user applications has resulted in an increase in the complexity of device designs, and the design productivity gap has only widened. The IP licensing model is seen as the next big hope in bridging this gap. The emergence of System-on-Chip paradigm (SoC) has given a further boost to the development of the licensable IP market. SIP is critical for the design and implementation of complex system ICs and can potentially provide a solution that enables companies to bridge the "design gap".

Despite the hurdles mentioned above, some Indian firms have developed a portfolio of reusable components that they license to chip design firms. For example, several Indian design firms like Wipro, Sasken, Mindtree Consulting license IP's based on standards like Bluetooth, USB, WLAN, MPEG, JPEG, etc. To understand the position of Indian firms in the IP Licensing Value Chain, it would be useful to review the types of IP that are licensable in the semiconductor industry.

SIP products are generally available in two forms - soft and hard[9]. Indian firms license mainly Soft SIP, as they have limited access to foundries, and their skills in hardware definition languages and embedded software are more mature. Within this they have focused mainly on standards-based connectivity SIP which helps in the revision of the standards, which may be continuously evolving. Software IP also refers to reusable Hardware Dependent Software (HDS) components ranging from embedded OS, wireless stacks, and application software, drivers, assemblers, compilers, and multimedia codecs. Indian firms like Wipro, Mindtree, Sasken are strong in software SIP. In DSP software SIP, several Indian firms market software compression/decompression code based on established ITUT standards. Indian companies did not develop the baseline compression/decompression algorithms, but these algorithms need to be optimized to a certain DSP processor, for which knowledge of the instruction set and design of the DSP processor is necessary. Other forms of embedded software in which Indian firms are strong include providing connectivity software and wireless protocol stacks as per the Bluetooth Specification. Indian firms are licensing these software-based SIP's extensively. Besides, some Indian firms like eInfochips are also licensing Verification SIP, which are essentially reusable components containing test suits for protocol-based designs. The verification components are configurable, reusable plug-and-play solutions for standard interfaces based on Hardware Verification Language. These verification solutions reduce the time to create the verification infrastructure.

It is common in the industry to develop custom-built SIP through a service contract and subsequently offer it as stand-alone product when it matures. Once the SIP matures, it may be classified as a "commercial" product that is offered with technical support, including maintenance updates when the foundry design rules change or when re-characterization is required due to process changes. Firms have implemented effective appropriability strategies to protect rents from their knowledge assets. Not only have they used legal intellectual property protection where possible, but also harnessed other mechanisms such as rapid time-to-market, complementary capabilities in sales and support, and network effects. Although the SIP Licensing Industry has grown after 2000, despite a downturn in the semiconductor industry between 2000 and 2003, Analysts and industry insiders believe that the third-party IP model has only limited potential, with the success of that approach confined to a few companies that either can offer "Star IP"' or can withstand the highly competitive market for commodity IP.

Some Indian firms are, however, are positive about their participation through licensing and sub-contracting in the embedded space. The primary driver for the demand for IP Licensing for Indian companies has been the increased amount of software that is being embedded onto devices, which earlier was hardwired into chips. This is especially true for mobile handsets, 3G Network Infrastructure, and wide area network communication stations. In these areas of technology, communication protocols have been standardized by international bodies like the IEEE, ITU, 3GPP, MPEG/ISO, ATM Forum, DSL Forum. These communication protocols can be implemented in hardware if speed is of essence, or they may be implemented using

[9] Goyal and Sharma (2004 provide details of different types of SIP.

embedded software. With increasing complexity of the algorithms that go into some of these standards, software implementations of standards are on the rise. For India firms, this development is increasing opportunities in software IP licensing. The emergence of System on Chip Paradigm has also increased the prospect for IP licensing for Indian firms. But SoC IP's are typically hardware design IP's or Silicon IP's, which is an area where Indian firms have historically not been very strong. Within each category of IP's (Software and Silicon), there is a hierarchy that separates star IP's from commodity IP's. Besides, the software IP licensing business has a significant gestation period before an IP can gain market acceptance, and undifferentiated IP's bring in little revenues. Moreover, most Indian firms seem to be engaged in the development of optimization algorithms, the appropriability of which (and consequently the revenue streams) are limited to the first time they are licensed.

4. Emerging Entrepreneurial Opportunities and IPR Regimes

The IP regimes typically have to deal with a *trade-off between invention and diffusion of technologies*. Very stringent IP regimes can reduce the opportunities for building on existing technologies. It is also a well-known fact that *effectiveness of IP regimes is often dependent on other complementary regulatory arrangements*. For example, policies that permit anti-competitive behaviour based on IP based monopolies can inhibit licensing and cross-licensing arrangements reducing the potential of technology diffusion. The debate on the Microsoft case in the US provides ample evidence on the relevance of such linkages.

The discussion above has highlighted the fact that with the convergence of technologies sectoral specificity of IP protection is breaking down. For example, IP protection in pharmaceutical and biotechnology sectors is no more patent centric. Given the ingress of IT based technologies, the IP protection in this sector has to deal with issues relating to patents, copyrights and integrated circuits protection. For example, new inventions in bio-informatics technologies are quite important for the cost of drug discovery. Similarly, the scope of IP protection in the IT sector is no more restricted to copyrights.
One may therefore need to understand the complex interplay between traditional patenting, software patenting, copyrights and integrated circuit protection.

In general, therefore, for any sector one needs to analyze the role of various types of IP in the protection of one's inventive activity. The protection of research databases, for example, is emerging as a very critical element in pharmaceutical research worldwide. The discussion also identified the emerging possibilities of research and production networks in the sectors we have identified, particularly in pharmaceuticals and biotechnology. The IT industry in India already has significant exposure to inter-firm networks. But the nature of these networks is likely to change with a higher focus on value-adding research activities.

Instead of focusing on all aspects of the new IP regime in India, we focus on a few contentious issues relating to the biotech-pharma and IT-electronics sectors. In the case of pharma-biotech sectors questions have been raised about the patentability of new uses of existing chemical entities, new drug delivery mechanisms and dosage forms. In addition,

protection of clinical trials data (data exclusivity) has raised some concerns. In the context of the IT-electronics sectors, the debate has revolved around patentability of business models and algorithms.

In what follows, we review these issues in the context of changes in technology and industrial structures discussed above and in view of recent changes in IPR regimes elsewhere.

4.1 IPRs in the Pharmaceutical-Biotech Sector

Among others, the following are excluded from patentability in the new patent law in India. These have significant implications for the pharmaceuticals and the biotechnology industries:

- A mere discovery of any new property or mere new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;
- A process for the medicinal or other treatment of human beings and animals;
- A mere discovery of a new form of a known substance, which does not result in the enhancement of the known efficacy of that substance

The Indian law, therefore, does not allow patents for new uses & therapeutic methods patents and seem to put significant constraints on the patentability of new dosage forms & drug delivery mechanisms. We saw in the earlier section that very few Indian firms are actually engaged in the discovery of new chemical entities; most are engaged in incremental inventions. Such a research strategy makes sense given that R&D costs of the pharmaceutical industry are on the rise. The development of this research strategy has been largely attributed to factors like increase in number of known pharmaceutical compounds over the years, knowledge of their toxicological profile and increase of standard of life sciences in the last four decades. Besides being cost-efficient and time saving, such new uses are easier to obtain regulatory approval than conventional new molecular entities. And this is a worldwide phenomenon; during 1989-2000, only 35% [361] of all the drugs [1,035] approved by the Food and Drugs Administration in the United States consisted new molecular entities or drugs consisting new active ingredients (NIHCM, 2002). The remaining 65% of drugs contained active ingredients that were already available in marketed products. Out of these, 558 drugs differed from the marketed product in dosage form, route of administration, or were combined with another active ingredient. Given these trends, the US and Europe were compelled to protect this investment through patents.

4.1.1 Issues Relating to New Use Patents – The US and European Experience[10]

The European Patent Office grants new use patents but makes a distinction between discovering a new use of a known substance [not known to be a pharmaceutical substance] and discovering a new use of a known pharmaceutical substance. The former is termed as *first medical indication* and the latter *subsequent medical indication.*

[10] This subsection is essentially based on Nagarsheth (2005).

To the former, product patent protection is granted; the EPO treats them like any new molecular entity. Only a method/use patent is granted to subsequent medical indications. The EPO requires higher standards of utility and disclosure for granting such use patents. The EPO Guidelines state that mere pharmaceutical effect does not necessarily imply therapeutic effect. It requires the patent application to state the therapeutic application in form of a defined and real treatment of a pathological condition. The breadth of patent claims disclosing subsequent medical indications are limited to the specific new use that is disclosed in the patent application. If a patent applicant intends to include more than one new use in a patent application, the patent applicant must clearly mention each one of them in the application. New use is broadly defined. Basically, if a compound manages to treat a new disease, the EPO would consider such uses novel. Furthermore, use of the same compound for a different class of patients or a new way of administering the drug also seems patentable.

Unlike the European law, where product patent is granted to known substance for the first new medical use and use patent for any subsequent uses, the US law does not distinguish between first medical use and subsequent medical uses of a known compound. The US law permits only *use/method patents* for known substances on grounds of lack of novelty and non-obviousness.[11] If the known substance is commercially applicable ***only*** for the purpose that is laid down in the process patent, such a known substance is regarded to be a 'non-staple article' and the patentee can bring action for contributory infringement against an alleged infringer for making and selling such a non-staple article.

Furthermore, if the patentee makes a slight change to the structure of the known substance that has a new use, product patent could be granted as long as it is non-analogous and complies with other requirements of patentability like novelty and non-obviousness. A unique incentive is also afforded to drug companies in the United States to incrementally innovate through the Hatch-Waxman Act. In case of branded drugs getting approved from the FDA, the modified version of the branded drug on the basis of new clinical studies, would receive three years of market exclusivity on 'the new use' of the product, beginning on the date of the approval. 'New use' in this context encompasses not only new indications but also other changes like dosage forms, method of administering the drug and incorporating a new combination drug. During these three years, no generic company can market a product that is directly competing with this new use. Thus, by modifying the same drug repeatedly, a brand manufacturer may be able to keep directly competitive generics off the market for a decade or more after the compound patent on the drug has expired. Furthermore, in cases of incremental innovation with no new use [for instance, less side effects or different mode of administering drugs], state governments who regulate pharmacy practice encourage pharmacists to

[11] The rule that no product patent may issue for discovery of a new use for an old product or process is tempered by the 'doctrine of slight changes'. It has been commented that so long as the old product has been altered (however slightly) to fit the new use discovered by the inventor, there is no novelty bar to obtaining the patent. Furthermore, the altered product may be patented if the discovery of new use and alteration when considered together indicate 'invention', that is, non-obviousness. If the new use is merely analogous to the known product's known use, then generally the discovery will fail to meet the standard of non-obviousness.

prescribe new version of the old drug. Hence, it is apparent that the regulatory laws and the patent protection play an important supporting role in fostering incremental innovation within the pharmaceutical industry.

The US law clarifies that *discoveries of natural and inherent chemical or biological properties per se is not a new use invention.* Thus, inventions that use same compounds for treating same disease but which merely discloses a new natural or inherent biological or chemical property of the substance are not patentable. Like European law, the US law also permits patents where the new use is not in discovering treatment for a new disease, but for a new class of patients. New modes of administering a drug can also be patented.

4.1.2 Appropriate Options for India

Admittedly, MNCs are on the forefront in discovering new uses of pharmaceutical compounds. The regulatory environment in the US and Europe seem to have facilitated such a research strategy. This strategy appears to be cost-efficient and less risk-prone, and slowly Indian pharmaceutical companies seem to be getting into this strategy and therefore may gain from grant of new use inventions. It is not known if such a strategy would become more common or if Indian firms would be able to compete with MNCs, It is clear, however, that banning patentability of new use inventions outright would at the margin lower incentives for Indian firms to engage in such research.

On the face of it, grant of patents for new uses of old drugs seems advisable. However, a strict test of Novelty and Inventive Step while assessing such inventions is also desirable. Given that the new Indian Patents Act does not allow patents to processes for medicinal and other such therapeutic treatments, claims relating to dosages, methods of administering drugs, patient groups, mere new knowledge of biological or chemical mechanism without any technical effect or improvement and new advantages to known use can be disallowed. It is advisable, however, that the new drug delivery systems (NDDS) that are patented have a *significant inventive step* and are not frivolous. It is not entirely clear how the efficacy of new NDDS and dosage forms would be determined.[12] These changes would create more options for Indian firms to participate in drug development research and utilize licensing and cross-licensing options. This will also create a better atmosphere for contract manufacturing of patented drugs and collaboration of Indian firms with MNCs in drug development activity. Given that laws of developed economies on new use inventions are not similar, it is less likely that such restrictive approach to new use inventions would fall foul to Article 27.3 of the TRIPS Agreement.

The Indian Patent Act has rightly incorporated the "Bolar" Provision, that effectively allows manufacturers to begin the research and development process in time to ensure that affordable equivalent generic medicines can be brought to market immediately upon the

[12] The admixtures are currently non-patentable under the Act. It is not clear how this would affect patentability of NDDS and dosage forms. To the extent that this prevents the patenting of inventive NDDS, this should be amended.

expiry of the originator product's patent. The efficacy of this provision is dependent on early availability of clinical trials data. Data exclusivity rules, therefore, should not be stringent. Duration of data exclusivity should be amended to allow the effective scope of patent protection to be limited to 20 years. MNCs and some Indian associations of pharmaceutical companies (OPPI) have sought amendments to the Drugs and Cosmetics Act to include a provision of Data Exclusivity for a period of six years from the date of marketing approval. Data Exclusivity on research data provided in order to secure marketing rights on pharmaceuticals is considered important by these players as it takes up to 10 years of time and investment to generate such data, which provides an important competitive advantage. Having no data exclusivity may not be TRIPS compatible but a shorter period of data exclusivity at this point of time would be desirable for the Indian firms. Short periods of exclusivity would also enhance the utility of the Bolar provision. However, such a change falls outside the purview of the Patent Act.

4.2 IPRs in the IT-Electronics Sector

Our discussion in the last section showed that in the semiconductor and embedded services industry the critical success factors in the SIP licensing business seem to be:

- Rapid time to market the IP (especially commodity IP's)
- Developing proprietary IP which can become a de-facto standard (Star IP's)
- Breadth of SIP portfolio (ability to bundle several IP's in one license)
- Ability to support Licensed IP
- Strength of Relationships with Customers of the IP's

With respect to the role of intellectual property in appropriability, the impact varies depending on the sub-segment within the semiconductor industry. Intellectual property rights protection through patents and copyrights is very important for vendors of entire systems like computer and mobile phones, or chipsets for such vendor. Patenting is also important for developers of star IP's like the ARM embedded processor, which go on to become de-facto standards for the rest of the industry. But for developers of commodity IP's the critical success factors listed above play a much more important role compared to IP protection. In the Hardware and embedded software design services industry, IP protection is not a critical factor for appropriability. These firms use standard components and build applications for which they can use mainly copyright protection of circuit designs and embedded software code. Indian firms mainly operate in the Services and commodity software IP space. But Indian IT firms seem to be in favour of stronger IP regimes. Recently, the Ministry of Industry, Government of India, organized discussions on the new IP regime with several stakeholders including industry associations to seek inputs on the modifications of the IP regime. Interestingly, in many cases, the industry associations sought more stringent IP regulation (Basant, 2004). In this subsection, we discuss some of these in the case of IT related IP.

Among others, the exclusions from patentability in the new Indian patent law include:

- A mathematical or business method or a computer programme per se or algorithms
- A mere scheme or rule or method of performing mental act or method of playing game
- A presentation of information
- Topography of integrated circuits.

Since there is a separate *sui generis* protection for integrated circuit design, these exemptions imply that software *per se* is not patentable; although software together with hardware enabling the machine to function effectively may be protected. The industry associations have, however, argued that there is a need to bring software into the fold of patentability for the following reasons:

- Copyright was designed to protect, with some exceptions, non-functional matter, whereas software or computer based business models are clearly functional works of technology.
- Copyright does not protect ideas, methodologies, processes, techniques and the like, which are often the most important features of software programmes and business models.
- While copyright only exists in the expression of an idea, a patent could be said to grant exclusive rights in the idea itself (provided that such idea can and has been tangibly expressed) thereby precluding others from exploiting a patented invention even if such invention has been developed independently.
- Copyright and patent protections are not mutually exclusive. Patents protect creative functional invention whereas copyright protects creative non-functional authorship.

Clearly, these arguments are significantly influenced by the IP regimes in the West, especially in the US. The recommendation was to revisit the clause that mathematical or business methods or computer programmes or algorithms per se are non-patentable subject matter as they may have underlying 'technical' principles and may easily qualify as technology under TRIPs. The current IP law in India provides for copyright protection for software. The expression/idea dichotomy used to distinguish copyrightability from patentability is sometimes ambiguous.

The last section highlighted the fact that Indian firms do a variety of jobs – both low and high end. Some even get into niche areas of technology and product development and some do captive development. Companies in each of these segments have different concerns about the IP laws and their implementation. Low-end companies are not really bothered about IPR laws as the work they are doing does not involve any Intellectual Property creating activity. Most of their work is repetitive and requires little skill. Though a situation in the future can be envisaged in which the companies like TCS, which have over a period moved towards higher end of the product development and even creating Intellectual Property, would like to focus on the high end work and would in turn want to outsource their non-core activities to these low end companies. This would be possible when the IPR laws in India get stricter over

a period of time which would give incentive to the companies like TCS, which have world class infrastructure and thus no longer need hand holding, to spend more on IPR generation.

Strengthening of the IPR laws is also a necessity as at present, large Indian companies owning to majority of their business clients in US and Europe, prefer to register their IP in the countries where they can find big market for the products and where they are more sure of their IP being protected and not plagiarized. In recent times, the Indian economy has also started growing at a healthy rate and is projected to be one of the fastest growing economies along with China in the next decade. Also, more and more MNCs that make durables like phones cars etc. where software is embedded are setting shop in India. Thus, in the coming future, these large Indian companies would no longer be able to ignore India for registration of their IP rights. Strong IP laws would make the MNCs comfortable in giving more and more business to Indian companies and even outsource higher end functions. The same can be said of companies with niche products/ markets as they are always worried about their product/technology getting copied by competitors. This is one sector, which can clearly see the benefits of strong IPR laws even at present and need not look into the future for that. Though at present these companies prefer to register their IP rights in USA as it is the biggest market as well as abode for large automobile manufacturing companies, with increasing outsourcing to India, these companies have huge scope to build products for these companies which do the outsourcing work. If the products built are to be used for analytics and testing, then most of those products will be used by Indian companies themselves. Of course, for that, the companies developing the products would have to register their IPs in India.

At the same time, services firms rarely develop proprietary technology and if they do, it often becomes the property of the client. Hence protection of IPR's is usually not of much concern to them. They use commercially available software tools to carry out most of their design activities. These tools are very domain specific and would be a huge undertaking to reverse engineer. Hence one finds that Western firms that have developed these tools do not hesitate to sell their software to India firms. There does not seem to be any hesitation on the part of these tool vendors from doing business with Indian design firms. In the chip design value chain for example, Indian firms doing physical design and design verification use commercially available EDA tools to provide their service. Since Indian firms have tried to spread themselves across the design value chain, they have not attempted to specialize in one activity like the US firm ReShape, which has focused on automated floor-planning solutions in chip layout design. By staying focused on one task of the value chain and investing in R&D to realize improvements in that task across multiple customer engagements, companies like ReShape have succeeded in developing their own products. Usually product-based companies have more to gain from strong IP protection regimes.

Overall, while there is limited need for IP protection but it may increase in the future. In India, software "per se" is not patentable although software together with hardware enabling the machine to function effectively may be protected. In practice, it seems many software patents are filed using the "embeddedness in hardware route. Article 52 of the European Patent Convention (EPC), and the practice that evolved by the European Patent Office (EPO)

can be used as an indicator of how Indian courts will interpret the meaning of "per se", which is akin to the phrase "as such" in EU law. Although the EPC does not define the term "as such," the case law has developed a workable definition of the term, which allows almost all kinds of programs that cause a "technical effect" to be patented. A program is considered to have a technical effect if it causes an effect that goes beyond the "normal" physical interactions between a program and a computer. One such example is a computer program, which decodes electronic signals more accurately to provide better relay. If this is going to be the interpretation, one does not see any need to have a provision wherein software *per se* is patentable. Most of the inventions covered in Appendix II and discussed in the last section should be covered with this interpretation and at the same time one would be able to avoid business method patenting, which is desirable.

The Indian software and semiconductor design industry has had a focus on services, as opposed to the design of complete products and systems. By the very nature of their work, services firms are not as affected by the IPR regime. The main concern for the services firms is movement of people across firms, and the possibility that trade secrets of one Western complete systems firms get passed on to another such firm or to a domestic Indian firm through employees compromising on exit clauses calling for secrecy, when they join a new firm. The slow legal system encourages these firms and their new employers from stealing trade secrets with impunity. Hence a speedier system of handling infringement suits will put a check on this IPR violation. A more distant possibility is the emergence of Indian firms designing complete systems for the domestic market. Pressure to enact stronger IP protection and better prosecute IP infringement lawsuits may come from an unexpected quarter: Western Governments and Industry Associations of Western manufacturers. It is in the best interests of India to put in place a more robust system of enforcement before the Indian market reaches a level of maturity where IPR infringements start to dominate the headlines.

Thus, while the laws themselves seem appropriate, the lax enforcement (due to the absence of special patent courts) weakens the impact of the overall IP regime. As the IPR enforcement regime languishes, design services firms have not stood idle. To assuage the concerns of their Western Clients, they maintain strong adherence to non-disclosure agreements signed with clients when a contract is entered into. Based on the review of the IT-Electronics industry, and the IP practices, a change to make software patentable does not seem to be necessary at this stage. However, we need to have

- Better procedures in Infringement Prosecution, through special IPR courts
- Introduction of trained IPR specialists in assessing claims, and arbitrating disputes

These changes would help all sectors. This is not to suggest that Indian firms are not developing IP. They are but the current system seems adequate to provide regulatory support

to them. Creation of IP by Indian firms is desirable in order to enhance the quality of their linkages with other firms.[13]

5. Some Concluding Observations

This paper explored the recent changes in the technology and industrial structure in the global IT-electronics and Pharmaceutical-biotech industries to understand the emerging trends. An exercise was then done to ascertain how the entrepreneurial opportunities for Indian firms have changed due these global changes. The final question was to assess if the existing IPR policies in India can potentially constrain the exploitation of these emerging opportunities by Indian firms. If yes, what changes are desirable? Our conclusion is that while IP laws specific to the IT-electronics sector may not need any change, patentability of novel new uses of existing compounds and inventive NDDS is desirable. Besides, a liberal regime on data exclusivity would enhance the opportunities provided by the Bolar provision in the new Patent Act.[14] An overall improvement of enforcing IPRs is certainly desirable. The rest of this section raises some general concerns about the new IP framework in India.

5.1 Need for Petty Patents

Studies of IP systems in Japan and elsewhere have shown that certain features of their systems facilitated technology diffusion (Maskus and McDaniel, 1999). The primary channel of technology diffusion in Japan was derived from applications for utility "models, which are incremental inventions that build on knowledge in existing patent applications and that can be put to commercial use quickly. (The U.S. patent system offers no equivalent to the utility model.) Japanese and foreign patents were used as the bases for modified technologies. The industries that most often built upon foreign patent applications and filed domestic utility model applications were in chemistry (including metallurgy) and the physics, communication, and measurement industries. One important indirect result of initial patent applications was the stimulation of follow-on utility models. All this encouraged diffusion that promoted "catching up" to advanced technologies. The 1994 amendments to Japan's intellectual property laws streamlined the utility model application process by eliminating the examination (effectively ending the need for publication of the application and opposition procedures) and shortening the length of protection from 15 years to 6 years from the application filing date. The shortened term of protection, coupled with increased registration and maintenance fees, has reduced the expected value of a utility model and thus caused a decrease in the number of utility applications in favor of patent applications (Aoki, 1997). For Indian firms such an option may still be useful. It can be argued that the Indian Patent Office

[13] For Geometric Software their IP is the main differentiator as compared to other service-oriented firms. This ability to build IP was one of the key reasons why mainstream PLM vendors entrusted the source codes of their software by establishing offshore development centers in Geometric IP is also the key reason why French PLM major Dassault decided to enter into a joint venture with Geometric. Similarly, Ittiam Systems has its entire business model based on IP licensing. In a short span of two years, the company has created a record portfolio of 30 IPs and 26 customer engagements.

[14] Interestingly, this policy advice is largely consistent with the views of the US venture capital firms whom we interviewed during the course of this project, except of course on the issue of data exclusivity where they would prefer a more stringent regime.

has limited resources and such a system would put pressure on them. There will be some additional burden but it may be desirable because such patents would enhance he utility of the pre-grant disclosure and opposition provisions that the Indian Act has included. Now, the local firms would look at these applications not only from the perspective of opposition but for incremental innovations. Similar provisions in Japan and South Korea resulted in significant cross licensing between original and the subsequent (incremental) innovators. This in turn facilitated learning and diffusion of patented technologies. The utility of this provision would get enhanced if the claims are narrowly defined, a feature all patent systems should work towards.[15]

5.2 Amendments in Compulsory Licensing:

The current IP laws in India, at any time after the expiration of **3 years** from the date of sealing of a patent, any interested person can make an application to the Controller for a Compulsory License on any of the following grounds:

- Reasonable requirements of the public with respect to the patented invention have not been satisfied.
- The patented invention is not available to the public at a reasonably affordable price.
- The patented invention is not worked in the territory of India.

While the first clause makes sense, the other two can be problematic. It is not clear if the last clause is TRIPS compatible. Using a price criterion while Drug Price Control Order is TRIPS compatible seems superfluous and makes the interpretation of "reasonably affordable price" quite cumbersome. Surprisingly, the provisions on compulsory licensing deem specific instances of anti-competitive behavior as not satisfying "reasonable requirements of public". A new clause needs to be added to broaden the scope of the first condition. This is particularly desirable because according to TRIPS, compulsory licensing undertaken due to anti-competitive practices need not have any restriction on the export of the patented product.

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[15] Koneru (1998) makes a very strong case for narrow claims to facilitate innovation and diffusion.

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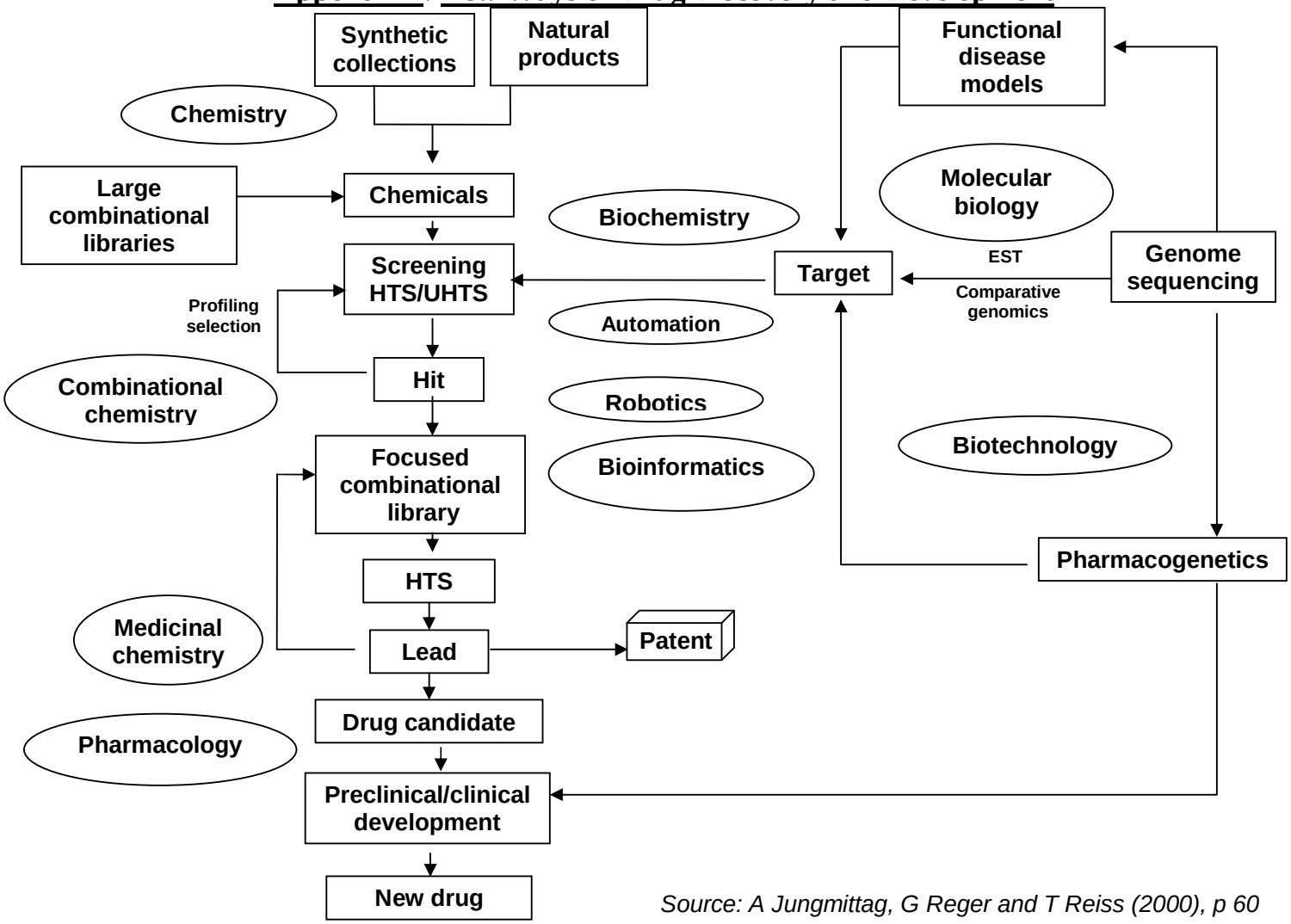
Appendix 1: New Ways of Drug Discovery and Development



Source: A Jungmittag, G Reger and T Reiss (2000), p 60

Appendix II: Nature of IP Generation and Protection by Local and Multinational IT Firms in India							
Firm Name	**Type of firm**	**Nature of Technology**	**Industrial Application**	**No and type of IP**	**Nature of use**	**Market**	**JV/R&D/Tie-up**
Wipro	Local	SoC and board design, core IP design	Consumer electronics, automobile, communications, defense	5 core-IP*	Sale + licensing	Cisco/Lucent/ Japan/ Korea/ Taiwan/Middle East	Hyundai/TSMC/ARM/Lineo/ST Micro (all for design services)/ASE (test packaging)/Mosis/GE/ Erriscson
Sasken	Local	Design and embedded	Communications, test and measurement	39 patents	Licensing	Japan/Canada	Symbian/TI/Intel (licensing partner)/U.K based Anite/DCM
Texas	MNC	Silicon design, embedded software, products	Communications, defense, telecom, networking, DSP (signal processing)	225 patents	Licensing	U.S/Europe	4-offcampus development centers/OMAP tech centers/3rd party developers/Nokia (supplies chips)
Neo Magic (Noida/ Kanpur)	MNC	SoC designs and products	Communications, multimedia, entertainment	55 patents		IBM/Dell/HP	Analog/Sony
Mistral	Local	Embedded software, board and chip design	Consumer Electronics, Automotive, Telecommunications, Wireless, Networking, Defense, Aerospace, Office Automation, Semiconductor, Internet Appliances and Industrial Applications	Re-usable components/ IP		Japan (Sony/Sanyo/ NEC)	WindRiver/ Analog/ Force/DENON/eTEC(VC)
Cadence (Gurgaon)	MNC	EDA* design tools, design services	Design tools, wireless communications		Sale	IC and systems designers, embedded services	Agilent/IITs/ IIT-Kharagpur (developed chipset)
Cypress	MNC	Chip design, software	Networking, computing, industrial	60 patents compiled			
Analog	MNC	Design and manufacturing of IC, embedded, high-speed semiconductors	Communications, multimedia	Developed 3 DSP producst		India/U.S/ Europe	IITs/several India companies (for design services)
National Semi-conductor	MNC	SoC solution	Computing, wireless, networking, multimedia, communications			Wireless, displays, PCs, networks and a broad range of portable applications	Collaborated with 3 Indian firms for localizing set-top-boxes
Motorola	MNC	Chip design and embedded	Communications, networking, computing, entertainment, automotive, consumer electronics			China/India/ Asia-Pacific/ Europe	Hutch/IISc
Cisco	MNC	Chip design	Networking, Telecom	9 patents filed			Promoting development centers with HCL, Infosys and Wipro/IITs/IISc
Synopsis	MNC	EDA tools, verification, chip design applications,	Design tools development			India/U.S/ Europe	IIT-Kharagpur (VLSI lab)/Sasken (sub-contracts)/ TI/ ST /Intel Wipro/DoE ControlNet (clients)/ Avanti (Hyderabad

		design services					acquisition)
HCL	Local	Core IP design, software,	Communications, Industrial	Reusable components			Magma (for design services)/Cisco, GM (clients)/ KLA Tencor, NCR, Convergys, Toshiba, Siemens VDO, NTT Data and Lexis-Nexis/ Deutsche Software and GIC (U.S) (JV)
Interra Systems	Local	SoC designs, embedded software	Electronics, video and memory applications	IP blocks		EDA toll designers	Synopsis (licensing)/IKOS/Cypress
Phillips Semi-conductor	MNC	SoC, embedded system engineering design, programming and testing	Communications, automobiles				Training IIT-Delhi students
AMD (recent design center2004)	MNC	Chip and system level design	Communications/networking				
IBM India	MNC		**Biotechnology**, Computing, communications, networking	75 patents	Licensing	India/Europe/U.S/Asia-Pacific/Japan	Wipro/NIIT
Ittiam (A Texas spin off)	Local	Chip designs and embedded systems	Audio-speech, image-video, wireless and wire line communication	30- IP/2 patents filed	Licensing	US, Europe, Japan, Taiwan and Korea	Silicon Lab (JV)
Control Net (Goa)	U.S start-up	SoC design, IP integration. Embedded software	Networking		IP creation in verification, wireless LAN etc.		
Mind Tree	Local	Designs re-usable building blocks for hi-tech companies, software	Communications			Developed a PDA for a U.S client/	Sun (tech partner)/Walden and Capital (venture)/ UMC/SAS /Volvo IT/ CadenceTexas/
ST Micro-electronics (Noida)	MNC	Embedded software, SoC design	Computing,	100 filed and 32 filed (2002)		Europe/US	
Ishoni	U.S start-up	Chip design and software for SoC	Broadband (cable/DSL)		Licensing	Europe/US/ India	Phillips Semiconductor (51% stake)/Alcatel/Wind River/ Draper Fisher Fund
Spike	U.S start-up	SoC design	Communications, storage, networking, multimedia, SoC		IP core		TSMC (foundry)
Impulsesoft	Local	IP creation/embedded software	Wireless communications devices/IP is in Bluetooth protocol stacks		IP licensing/ royalties	OEM/silicon vendors	Smart Modular, Matsushita and BenQ/ Braodcom/ Infeneon/National/TI
Geometric (Bombay)	Local	IP blocks	Mechanical, manufacturing and industrial		IP licensing/ sale	US/Europe/ Japan	Wipro/ Dassault Systemes(partnership)
vMoksha	Local		Enterprise solution		One patent filed (authentica-tion protocol)	India, the UK, the US, Australia and Singapore/ Japan/China	JV with Chinadotcom/ Challenger Systems
Arcus (Dublin	Start-up-	Chip design	Networking			Nortel, Lucent,	Foundry partners-Goldstar/LG

based-taken over by Cypress)	MNC					Fujitsu, Siemens, Cisco and Sony	Semicon/UMC
Intel	MNC	Chip design and manufacturer, embedded	Semiconductors, telecom switching, equipment and routers, computing, communications	21 patents filed		India/Asia Pacific/Mobile computing market	Network Solutions (Acq. b'lore)/IITs/Thinit (acq. Blore /IISc
TCS	Local	Software solution	Banking/insurance/telecom/manufacturing/Biotechnology	35 patents filed		India/Europe/Asia - Pacific/ U.S/China	Adobe/EX NGN/Microsoft
GE India	MNC		Controllers, consumer electronics, transport				Wipro
Sun Micro-systems	MNC	Server design	Computing, **Biotechnology**	10 filed			HCL/Wipro/supercomputing facility at IIT-Delhi
BiSquare (Delhi)	Local	System (ASIC) design, Embedded software	Communications		IP creation and re-use		
Silicon Interfaces	Local	Software and VLSI design	Networking, communications, storage		12 IP	Europe/Asia-Pacific Rim/ U.S/Japan	Semiconductor consortium/
Aftek Infosys	Local						
e-Infochips	U.S startup	Embedded, software, ASIC design			Developed re-usable IP cores		TI/Mentor Graphics/ semiconductor consortium/ verisity
Alliance Semi-conductor	U.S startup		Communications, computing, consumer and industrial				UMC/Charted Manfng. (Singapore)/Tower (Israel)
Siri Technologies	Local (B'lore)		**Biotechnology**, embedded, logistics				
CDC Linux	Local (B'lore)	Super computing, embedded software	Embedded, computing and **Biotechnology**				
Mason Global	U.S startup	Embedded, bioinformatics, applications	Telecom, Insurance, manufacturing, finance, computing and **Biotechnology**				
Satyam Computer Services	Local	Software solutions	Telecom, Insurance, manufacturing, finance and **Biotechnology**				Centre for Cellular and Molecular Biology (CCMB
Infosys	Local	Software solutions	Telecom, Insurance, manufacturing, finance and **Biotechnology**				
Silicon Graphics Systems	MNC	Supercomputing	Multimedia, Energy, manufacturing, defense, **Biotechnology**				GVK Bioscience (Hyderabad)
CMOS	MNC	Design	Telecom, networking, computing			U.S/Japan/ Europe/Asia- Pacific	Alpine Semiconductor/ Brocade/Phillips/Sony/ Panasonic
Excore Consulting	Local	Designing, computing	**Biotechnology,** communications, computing, networking				

EDA*= Electronic Design Automation that automates the process of IC and systems designs.

Core IP* design = It is a chip design that can be used as a core in almost all product development.